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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
10/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Karla.Dirks@Roche.com
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Office Action Summary	Application No.	Applicant(s)	
	10/559,547	HOENES ET AL.	
	Examiner	Art Unit	
	KAREN TOTH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *25-50* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *25-50* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 February 2011 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 25, 26, 28, 32, 34, 35, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boiarski (US 4727730) in view of Bicher (US 3878830).

Regarding claim 25, Boiarski discloses a system for analysing a sample to be examined comprising a test field containing a reagent which on contact, interacts with an analyte contained in a sample resulting in an optically detectable change in the test field (column 3, lines 44-61); at least one light-conducting element (elements 35, 36, 37, 38) having a distal end on which the test field is coated, wherein the test field is permanently adhered to form a layer on the distal end (figures 1, 2), and a proximal end

into which light can be coupled (via element16) such that light is conducted from the proximal end to the test field and is conducted away again from the test field by the same or another light-conducting element (column 3 line 67 to column 4 line 7); and a lancet which at least partially surrounds the light-conducting element (element 10) having a lancet tip which is located in a region of the distal end and of the test field in such a manner that the lancet tip extends beyond the distal end of the light guide and beyond the test field during a lancing process (figure 1; column 1, lines 52-56; the probe is passed through the catheter after it is inserted; thus, during the lancing/insertion process the probe/light-conducting element remains proximal of the lancet/catheter tip), wherein the lancet has an opening that enables the test field on the distal end of the light-conducting element to protrude beyond the lancet tip for contacting the sample (best shown in figure 1), wherein the opening of the lancet is unobstructed to allow the test field on the distal end of the light-conducting element to protrude beyond the lancet tip (figure 1).

Boiarski does not disclose how the light-conducting element is made to move through the lancet, particularly a driver configured to move the test field on the distal end of the light-conducting; element from a first position where the test field is located inside the lancet to a second position where the test field on the distal end of the light-conducting element protrudes beyond the lancet tip. Bicher teaches a driver (element 60) for moving a test element (element 12) from a first position inside a hollow body to a second position protruding beyond the tip of the hollow body (column 6 line 55 to column 7 line 12), in order to ensure consistent movement of the test element during

extension, thereby increasing patient comfort. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Boiarski with a driver for moving the test element from inside to outside the lancet, as taught by Bicher, since Boiarski does not disclose how to move the test element through the lancet and inclusion of a driver such as that of Bicher would ensure a consistent speed of movement and increase patient comfort.

The Examiner notes that Boiarski's 20 gauge cannula with a tapered insertion end, though not described as a lancet, is structurally equivalent to one, having both a small diameter and a tapered end for easing insertion.

Regarding claim 26, Boiarski further discloses a plurality of test fields (elements 28, 29, 30).

Regarding claim 28, Boiarski discloses a system for analysing a sample to be analysed comprising a test field containing a reagent which on contact, interacts with an analyte contained in a sample resulting in an optically detectable change in the test field (column 3, lines 44-61); at least one light-conducting element (elements 35, 36, 37, 38) having a distal end permanently connected to the test field (column 6 line 10 to column 7 line 21), wherein the test field is permanently adhered to form a layer on the distal end (figures 1, 2), and a proximal end into which light can be coupled (via element16) such that light is conducted from the proximal end to the test field and is conducted away again from the test field by the same or another light-conducting element (column 3 line 67 to column 4 line 7); and a lancet (element 10) having a lancet tip which is located in

a region of the distal end and of the test field in such a manner that the lancet tip extends beyond the distal end of the light guide and beyond the test field during a lancing process (figure 1; column 1, lines 52-56; the probe is passed through the catheter after it is inserted; thus, during the lancing/insertion process the probe/light-conducting element remains proximal of the lancet/catheter tip), the lancet being hollow (figure 1), wherein the light- conducting element extends within the lancet (column 1 lines 52-57), wherein the lancet has an opening that enables the test field on the distal end of the light-conducting element to protrude beyond the lancet tip for contacting the sample (figures 1, 2).

Boiarski does not disclose how the light-conducting element is made to move through the lancet, particularly a driver configured to move the test field on the distal end of the light-conducting; element from a first position where the test field is located inside the lancet to a second position where the test field on the distal end of the light-conducting element protrudes beyond the lancet tip. Bicher teaches a driver (element 60) for moving a test element (element 12) from a first position inside a hollow body to a second position protruding beyond the tip of the hollow body (column 6 line 55 to column 7 line 12), in order to ensure consistent movement of the test element during extension, thereby increasing patient comfort. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Boiarski with a driver for moving the test element from inside to outside the lancet, as taught by Bicher, since Boiarski does not disclose how to move the test element through

the lancet and inclusion of a driver such as that of Bicher would ensure a consistent speed of movement and increase patient comfort.

The Examiner notes that Boiarski's 20 gauge cannula with a tapered insertion end, though not described as a lancet, is structurally equivalent to one, having both a small diameter and a tapered end for easing insertion.

Regarding claim 32, Boiarski further discloses a plurality of test fields (elements 28, 29, 30).

Regarding claim 34, Boiarski further discloses the lancet and the light-conducting element being arranged concentrically relative to one another (figures 1 and 2).

Regarding claim 35, Boiarski further discloses that the lancet and the light-conducting element are arranged in direct vicinity to one another in a plane perpendicular to the lancing direction (figures 1 and 2).

Regarding claim 37, Boiarski does not explicitly disclose the system being used for determining a blood glucose concentration, but the system is capable of, or suitable for, determining a concentration of any desired analyte, including glucose.

Regarding claim 38, Boiarski further discloses that the system can be coupled to an analytical unit such that light can be coupled into the light-conducting element ,and the light conducted away from the test field can be detected by the analytical unit (element 17; column 4, lines 11-25).

4. Claims 27, 33, 36, and 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boiarski in view of Bicher, as applied above, and further in view of Kuhr (US 7396334).

Regarding claim 27, Boiarski in view of Bicher discloses all the elements of the claimed invention, as described above, except for the system having a plurality of lancets. Kuhr teaches a system for analyzing a sample where the system comprises a plurality of lancets (figure 6), in order to allow testing to be performed a plurality of times. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Boiarski in view of Bicher with a plurality of lancets, as taught by Kuhr, in order to allow testing to be performed a plurality of times. The Examiner notes that Kuhr includes teachings that lancets may be hollow with testing components (column 7 line 41 to column 8 line 9) in addition to the solid lancet discussed in examples.

Regarding claim 33, Boiarski in view of Bicher does not disclose a plurality of lancets in the system. Kuhr teaches a system having a plurality of lancets (figure 6), in order to allow multiple tests to be performed without having to procure a new system. it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Boiarski, as modified, with a plurality of lancets, as taught by Kuhr, in order to allow multiple occurrences of testing without needing to resupply lancets.

Regarding claim 36, Kuhr further teaches the lancet tip being embedded in a sterile protection prior to insertion (column 6, lines 12-19), in order to prevent

contamination. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Boiarski in view of Bicher with the lancet tip embedded in a sterile protection prior to insertion, as taught by Kuhr, in order to prevent contamination.

Regarding claim 39, Boiarski, as modified, does not disclose how to insert the system, particularly the system being used in a lancing device. Kuhr teaches a lancing device for inserting similar systems (column 8 lines 17-26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Boiarski in view of Bicher in a lancing device, as taught by Kuhr, since Boiarski and Bicher do not disclose how to insert the system and lancing devices are commonly used in the art of monitoring analytes.

Regarding claim 40, Boiarski further discloses that the system comprises an analytical unit such that light can be coupled into the light-conducting element ,and the light conducted away from the test field can be detected by the analytical unit (element 17; column 4, lines 11-25).

Regarding claim 41, Boiarski further discloses that the lancing device can be coupled to an analytical unit such that light can be coupled into the light-conducting element ,and the light conducted away from the test field can be detected by the analytical unit (element 17; column 4, lines 11-25).

Regarding claim 42, Kuhr further teaches a system for analyzing a sample where the system comprises a teaches a system for analyzing a sample where the system comprises a lancet configured to be inserted by a drive unit in a lancing device (column

6, lines 1-8), in order to ensure an uninterrupted insertion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Boiarski in view of Bicher and Kuhr with a drive unit for the lancet, as further taught by Kuhr, in order to ensure an uninterrupted insertion.

Regarding claim 43, Bicher teaches a drive unit for the light-conducting element (element 60); the device of Boiarski in view of Bicher and Kuhr would therefore include the drive device in the drive unit.

Regarding claim 44, Bicher teaches a drive unit for the light-conducting element (element 60); the device of Boiarski in view of Bicher and Kuhr would therefore include the drive device in the drive unit.

Regarding claim 45, Bicher's drive unit moves both of Boiarski's light-conducting element and test field when modifying Boiarski.

Regarding claim 46, Bicher's drive unit moves both of Boiarski's light-conducting element and test field when modifying Boiarski.

Regarding claim 47, Coleman discloses all the elements of the claimed invention, as described above, except for the system being in a magazine of the lancing device with a plurality of such systems. Kuhr teaches a system for analyzing a sample where the system contains a plurality of lancing devices in a magazine (figure 6), in order to allow testing to be performed a plurality of times. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Coleman with a plurality of the systems (the lancet/conducting element combination,

structurally equivalent to Kuhr's lancet) in a magazine, as taught by Kuhr, in order to allow testing to be performed a plurality of times.

5. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boiarski in view of Bicher, as applied above, and further in view of Garcia (US 4627445).

Boiarski in view of Bicher discloses using a reagent, but does not specifically disclose whether any interactions are reversible or irreversible; Boiarski also discloses that any desired reagent may be used, depending on the analyte to be sampled. Garcia teaches using a reagent to analyze a sample, where the reagent's interaction with the analyte sample is essentially irreversible (column 7 line 14 to column 8 line 34), in order to achieve a desired reaction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Boiarski in view of Bicher with a reagent configured to react essentially irreversibly with the analyte, as taught by Garcia, in order to achieve a desired reaction. The Examiner notes that, because the reaction is essentially irreversible, the system is therefore suitable only for single use.

6. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boiarski in view of Bicher, as applied above, and further in view of Wagner (US 4981779).

Regarding claim 48, Boiarski, as modified, discloses all the elements of the claimed invention, further suggesting use of multiple light-conducting elements (column 7, lines 14-16), but does not disclose the light-conducting element including a primary light guide configured to conduct primary light onto the test field and a secondary light guide configured to conduct secondary light that is reflected from the test field. Wagner teaches using two light guides to conduct light to and reflect light from a test field (figure 4 and 5, elements 12a and 32 or element 14a and 32a), in order to ensure that primary light does not interfere with reflected light. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Boiarski, as modified, with two light guides for separately delivering and receiving light, as taught by Wagner, in order to minimize interference.

Regarding claim 49, Wagner's light guides are separated by a barrier layer having a refractive index less than that of the light conducting element (column 6, lines 44-51; column 7, lines 13-16).

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boiarski in view of Bicher and Wagner, as applied above, and further in view of Feldstein (US 6192168).

Feldstein teaches the barrier being any desired material having a suitable refractive index, but does not teach the material including a metallic reflecting material. Feldstein teaches using a metallic reflecting material to clad an optical fiber (column 5, lines 57-61). It would have been obvious to one of ordinary skill in the art at the time the

invention was made to have made the system of Boiarski in view of Bicher and Wagner with a metallic barrier material, as taught by Feldstein, since it is merely the simple substitution of one known element for another to obtain predictable results.

Response to Arguments

8. Applicant's arguments with respect to the rejection(s) under Coleman (US 4622974) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Boiarski in view of Bicher, as presented above.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4403984 to Ash, which discloses similar structures.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Miranda Le/
Supervisory Patent Examiner, Art Unit 3735

/K. T./
Examiner, Art Unit 3735